ACMT Position Statement: The Iom Report on Thimerosal and Autism

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The American College of Medical Toxicology (ACMT) is a professional society composed of physician toxicologists who focus on the diagnosis and management of acute and chronic adverse health effects due to medications, chemical, occupational and environmental toxicants and biological hazards. The ACMT commends the efforts of the IOM report of *Immunization Safety Review: Vaccines and Autism* [1]. The ACMT notes that the Immunization Safety Review Committee, while comprised of many competent academicians, had none with the special skill set of a medical toxicologist, a critical criterion when the adverse effects of an organomercurial are being considered. The IOM is encouraged to include medical toxicologists on committees that focus on potential toxicologic exposures. Indeed, in the past, a medical toxicologist has stepped forward on this issue [2].

The IOM concludes that the body of epidemiological evidence indicates that there is no causal relationship between thimerosal containing vaccines and autism. The ACMT provides the following background and comments. Thimerosal is a mercury-containing organic compound (sodium ethylmercuric thiosalicylate, also known as Merthiolate, Mercurothiolate) which contains approximately 50% mercury by weight [3]. The United States Code of Federal Regulations (CFR) requires the addition of a preservative to multi-dose vials of vaccines. Since the 1930's, thimerosal has been widely used as a preservative in a number of biological and drug products, to help prevent contamination from microbes. When the Food, Drug and Cosmetic Act was passed in 1938, thimerosal was placed on the GRAS (generally recognized as safe) list. Thimerosal in concentrations of 0.001% (1 part in 100,000) to 0.01% (1 part in 10,000) has been shown to be effective in clearing a broad spectrum of pathogens. Placed in perspective, a vaccine containing 0.01% thimerosal as a preservative contains 50 micrograms of thimerosal per 0.5 mL dose or approximately 25 micrograms of mercury per 0.5 mL dose, in the form of ethyl mercury. As the number of vaccinations given to infants has increased, so has the cumulative exposure to Thimerosal as the organomercurial preservative [4].

In 1999, with a recognized increase in the prevalence of autism spectrum syndromes, attention was called to thimerosal as a potential risk factor, especially in combination with measles, mumps and rubella (MMR) vaccination [4–9]. At that time the Public Health Service (including the Food and Drug Administration [FDA], National Institutes of Health, and the Centers for Disease Control and Prevention [CDC]), and the American Academy of Pediatrics (AAP) called for the withdrawal of thimerosal from further use in vaccines targeted for children. However, thimerosal in existing vaccine inventory was allowed to be used.

Much of this concern was based on methylmercury-related neurotoxicity, the timing of vaccination during the first year of life when the blood-brain barrier is more permeable to heavy metals, and a model that equated intermittent exposure to ethylmercury to cumulative dosing of methylmercury. Recent research has confirmed that the ethylmercury component found in Thimerosal is less hazardous than methylmercury. These are different compounds and should not be considered as equivalent neurotoxins. Experimental conditions can be created that result in neurological cell dysfunction [10,11]. However, current literature supports the contention that childhood vaccinations do not deliver a sufficient dose to produce these neurological injuries.

Several large epidemiological studies have been completed in an attempt to clarify the issue of childhood immunizations and the risk of neurodevelopmental disorders. The CDC reviewed computer-based vaccination records and ICD-9 codes of autistic spectrum disorders for over 124,000 infants at two health maintenance organizations (HMOs) in California [12]. In 2003, a published comparison of imputed thimerosal dose in Sweden, Denmark and the United States found no correlation with the rise in prevalence of autism spectrum disorders occurring in all three countries [13]. The Institute of Medicine (IOM) of the National Academy of Sciences assembled an Immunization Safety Review Committee that held hearings and provided a series of reports, culminating in their 2004 *Immunization Safety Review: Vaccines and Autism* [1].

Although a number of potential concerns have been raised regarding the adequacy of the IOM review (7 months, rather than one year catchment period, and procedural issues such as

cutoff age and ICD-9 diagnostic listings), the ACMT believes that the IOM's conclusions are justified. In fact, in conjunction with epidemiological data from Europe, Australia, and the United States, the IOM report stands as reassurance to parents concerned about the risk of previous vaccinations for their children [14].

Although the AAP and the combined Public Health Service agencies (CDC, NIH and FDA) have taken a precautionary approach in encouraging vaccination of infants with Thimerosal-free products when available (particularly for the most susceptible infants—those that are very premature and undernourished), the ACMT wishes to emphasize that these are also those infants most at risk of vaccine-preventable diseases. The restriction of vaccine access is inappropriate and results in real, as opposed to theoretical, harm [15,16].

The ACMT further discourages chelation therapy in autistic children, a practice that is not supported by clinical evidence either of mercury toxicity or therapeutic effect, which can have hazardous consequences [7].

Lastly, the ACMT commends the IOM report's conclusions encouraging research funding to investigate adverse vaccine concerns, evaluating autistic disorders up through a pre-school catchment age, and related epidemiologic surveillance.

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